NCCTG Status Report for Study N0531 - April 2009

Phase II Trial of Weekly nab (nanoparticle albumin bound)-Paclitaxel (nab-paclitaxel) (Abraxane) in Combination with Gemcitabine in Patients with Metastatic Breast Cancer

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Study Closed: 05/26/2006

Study Status: * Study results were presented at the ASCO 2007 meeting.


* Nanoparticle albumin-bound (nab)-paclitaxel has better efficacy and practically eliminates the risk of hypersensitivity reactions associated with solvent-based paclitaxel. We studied weekly nab-paclitaxel and gemcitabine combination in an open-label one-stage, phase II trial in patients with previously untreated metastatic breast cancer (MBC). Nab-paclitaxel (125 mg/m(2)) and gemcitabine (1000 mg/m(2)) were administered on days 1 and 8 of a 21-day cycle until disease progression. Fifty patients were enrolled. Forty (80%) had visceral organ involvement and 30 (60%) had >or= 3 sites of metastases. Four (8%) and 21 (42%) patients had complete and partial responses by Response Evaluation Criteria in Solid Tumors (RECIST) criteria. Median duration of response was 6.9 months [95% confidence interval (CI) 5.7, not reached], median progression-free survival (PFS) 7.9 months (95% CI 5.4-10 months), and median overall survival (OS) was not reached. PFS and OS at 6 months were 60% (95% CI 48% to 76%) and 92% (95% CI 85% to 100%), respectively. Therapy was well tolerated. Neutropenia was commonest toxicity (42% and 12% grades 3 and 4 neutropenia). Only one patient developed febrile neutropenia. Significant activity and favorable toxicity profile provides a basis for considering this regimen for further evaluation in phase III trials or in combination with biologic agents.